IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the Patent Application of: Applicant: Jeffry D. Watkins et al. Serial No.: 09/995,529 Filed: November 26, 2001 Title: Humanized Collagen Antibodies and Related Methods	Group Art Unit: 1643 Confirmation No. 2007 Examiner: Stephen Rawlings **Certificate of Electronic Filing** I hereby certify that the attached **Response to Interview Summaries**, and all marked attachments are being deposited by Electronic Filing on **October 26, 2006**, by using the EFS – Web patent filing system and addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450. By: Norman Green Norman Green

RESPONSE TO INTERVIEW SUMMARIES

Mail Stop Amendment
Commissioner for Patents
P. O. Box 1450
Alexandria, VA 22313-1450

Sir:

This communication is being filed in response to the two Interview Summaries mailed by the U.S. Patent and Trademark Office on September 26, 2006 in connection with the above-referenced patent application. Please consider the following remarks.

Remarks begin on page 2 of this paper.

REMARKS

Applicants thank Examiner Rawlings and Supervisory Patent Examiner Helms for the telephonic interview of September 20, 2006 in reference to this application. The interview was continued on September 21, 2006 in connection with related application U.S.S.N. 10/011,250.

Examiner Rawlings stated on page 3 of the Interview Summary:

> Applicant's representatives discussed the grounds of rejection set forth in the Final Office action mailed August 30, 2006, in light of proposed amendments to the claims. It was strongly suggested that claim 89 be amended to recite the functional limitation that the antibody or fragment thereof binds collagen and has **at least a 2-fold** higher affinity for denatured collagen over native collagen. The Examiner agreed to carefully consider Applicant's arguments upon receipt of a written response to the Office action. [Emphasis added]

Applicants respectfully disagree with the Examiner's characterization of the interviews.

During the interviews of September 20 and 21, Applicants and the Examiner discussed Figures 8 and 9, which illustrate binding of modified antibodies to denatured collagen over native collagen. Applicants also pointed the Examiner to paragraph [0036] of the application as filed which discloses that the antibodies can have a higher binding affinity for denatured collagen versus native collagen. In view of the disclosure of the specification and the data presented in Figures 8 and 9, Examiner Rawlings and Supervisory Patent Examiner Helms acknowledged that the application as filed provides working examples of modified antibodies having higher binding affinity for denatured collagen versus native collagen and agreed that the claims did not have to recite "at least 2-fold" higher binding affinity.

During the interview, Applicants discussed Figures 4C and 6 of the application as filed with Examiner Rawlings and Supervisory Patent Examiner Helms. Modifications of amino acid residues in one or more heavy and/or light chain CDRs of HUIV26 variants presented in the figures represent modifications made compared to the wild-type sequence. Therefore, the figures demonstrate possession of a genus of antibodies which are supported by sequences of modified CDRs presented in the Figures, the description and the Sequence Listing. One of ordinary skill in the art reading the Figures would understand that, at the time the application was filed, the sequences of each of the

modified CDRs was presented in the application. No new matter has been added by amendment in contrast to the Examiner's assertions of record. Furthermore, Applicants have shown how to make and use modified antibodies over the full scope of the claims using the methods described in the application as filed.

In the second Interview Summary mailed on September 26, 2006, Examiner Rawlings stated on the last page:

> The Examiner proposed an Examiner's amendment and explained the reasons the amendment would obviate the issue of record, noting in particular the need to differentiate between the claimed invention and antibodies disclosed in the prior art. Applicant's representatives declined to authorize entry of the proposed amendment, indicating that they would prefer to file an After-Final Amendment but suggested that they would use the proposed amendment as a guide in their preparation of their amendment.. [*sic*]

In the interview, the Examiner indicated that the modifications (discussed above) presented in the proposed amendment were found in Figure 4C of the application as filed. As discussed in the interview, Applicants respectfully submit that the application as filed presents a greater number of modifications in the CDRs than found in Figure 4C. Support for other CDR modifications can be found, for example, in Figure 6, in paragraphs [0043], [0049] and [0061] to [0078] of the published application, the originally-filed claims, and the Sequence Listing as filed. Applicants faxed the Examiner a series of Tables which illustrated modifications made to the heavy and light chain CDRs and which included references to the sequence identifiers containing the modifications. Because the specification as filed, as a whole, includes modifications that were not presented in the Examiner's proposed amendment, Applicants reserved the right to file a response to the Final Office Action rather than accept the Examiner's amendment.

Applicants thank Examiner Rawlings for acknowledging that the modified HUIV26 antibodies are novel and for agreeing to allow composition claims of antibodies reciting specific combinations of CDRs which were presented in the specification as filed.

Applicants thank Examiner Rawlings and Supervisory Patent Examiner Helms for acknowledging that the application as filed provides working examples of modified antibodies having conservative and/or non-conservative modifications.

CONCLUSION

Applicants do not believe that any fees are due in connection with this communication. If, however, any fees are due, the Commissioner is authorized to charge any additional fees which may be required, including petition fees and extension of time fees, to Deposit Account No. 23-2415 (referencing 30797-711.201).

The Examiner is invited to call the undersigned agent at 858.350.2300 with any questions.

Respectfully submitted,

WILSON SONSINI GOODRICH & ROSATI
Professional Corporation

Dated October 26, 2006

Jeffrey W. Guise
Attorney for Applicant
Registration No. 34,613

650 Page Mill Road
Palo Alto, CA 94304
(650) 493-9300
Customer No. 021971